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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/730,760 | 12/08/2003 | John A. Dyjach | 279.663US1 | 3450 |

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| EXAMINER | |
|---|---|
| SMITH, TERRI L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3762 | |

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TWS

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/730,760 | DYJACH ET AL. | |
| | Examiner | Art Unit | |
| | Terri L. Smith | 3762 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *06 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) *1-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10-06-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 1–28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06 October 2005.

### *Drawings*

2. The drawings were received on 06 October 2005. These drawings are acceptable.

### *Specification*

3. The specification changes were received on 06 October 2005. The specification is acceptable.

### *Claim Rejections - 35 USC § 102*

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 29–30 are rejected under 35 U.S.C. 102(b) as anticipated by Schroeppel et al., U.S. Patent 5,749,900 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schroeppel et al., U.S. Patent 5,749,900 in view of Stone et al., U. S. Patent 6,280,409.

Schroeppel discloses an implantable cardiac rhythm management (CRM) device, a plurality of interface channels, a plurality of electrodes on at least one lead, a memory, a controller, and a communication circuit (Fig. 1; column 5, lines 12–column 6, lines 1–39 and 48–67; column 7, lines 1–16). Schroeppel measures "A–A, P–P, V–V, or R–R interval of the heart signal" (column 6, lines 61–63) which are CRT-related data parameters associated with time and, therefore, meets the claimed limitation of wherein data trends include at least one CRT-related data parameter associated with time (column 6, lines 48–column 7, lines 1–16, 28–50, 57–59, 61–66; column 8, lines 1–3 and 55–62).

Schroeppel discloses chronic, ambulatory data (column 6, lines 26–31).

In the alternative, for claim 29, Schroeppel discloses an implantable cardiac rhythm management (CRM) device, a plurality of interface channels, a plurality of electrodes on at least one lead, a memory, a controller, and a communication circuit (Fig. 1; column 5, lines 12–column 6, lines 1–39 and 48–67; column 7, lines 1–16). Schroeppel does not disclose data trends include at least one CRT-related data parameter associated with time. However, Stone

discloses data trends include at least one CRT-related data parameter associated with time (Figs. 4a–c) to provide feedback to the clinician during use of therapy (column 8, lines 35–36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Schroeppel to include data trends include at least one CRT-related data parameter associated with time, as taught by Stone to provide feedback to the clinician during use of therapy.

8. Claims 29–60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann et al., U.S. Patent 6,480,742, in view of Stone et al., U. S. Patent 6,280,409.

Stahmann discloses an implantable cardiac rhythm management (CRM) device, a plurality of interface channels, a plurality of electrodes on at least one lead, a memory, a controller, a communication circuit (claims 1, 49 and 54), a programmer (claim 49), a monitor (claim 49), a right ventricle interface channel (claim 31), a left ventricle interface channel (claim 31), a right atrium interface channel (claim 31) (Fig. 1; column 3, lines 35–67; column 4, lines 1–11); data relevant to a status of prescribed CRT includes a chronic, ambulatory data (claims 30, 50 and 55) (column 3, lines 7–11 and 14–17); the controller is adapted to do the following in or to the memory: record prescribed CRT data and time information (claims 32 and 58), record realized CRT data and time information (claims 33 and 59), record a pacing mode and time information (claim 34), record when the device is operating in an atrial tracking mode (claim 35), trend samples or CRT-related data relevant to the status of the prescribed CRT (including to trend N samples per unit time claim 36), N samples per unit time until a predetermined change occurs (claim 37) in or threshold is reached related to delivered CRT (claim 38) or a

predetermined event occurs (claim 39) and then trend M samples per unit time (claims 37–39), to trend M samples per unit time after initiation of trigger (claim 40), to trend a first parameter before a trigger and a second parameter after the trigger (claim 41)), a value corresponding to CRT delivery (claim 42), ventricular pacing at least one from a group consisting of left ventricular pacing (claim 43), atrial tachycardia (claim 44), capture (claim 45), a value above a programmed above a programmed rate being at least one from a group consisting of a programmed maximum pacing rate (claim 46), a mode of operation being at least one form a group consisting of a tracking mode (claim 47), and a CRT delivery results being at least one from a group consisting of CRT therapy that was successfully delivered (claim 48) and each value being at least from a group consisting of a percentage value and an absolute value (claims 42–48); memory of a CRM device includes controller instructions to be executed by a controller of a CRM device to trend data samples (claim 51); memory of a programmer includes controller instructions to be executed by a controller of a programmer to trend data samples (claim 52); means for detecting a trigger and trending data samples based on a trigger (claim 60) (Figs. 1–5; column 2, lines 25–36; column 3, lines 20–column 4; column 5, lines 11–12; column 6, lines 5–28; column 9, lines 45–column 10 lines 1–58; column 11; column 12).

Stahmann does not disclose data trends include at least one CRT-related data parameter associated with time (claims 1, 49 and 54) nor means for displaying information includes a graph (claim 56) and table of (claim 57) trended data. However, Stone discloses data trends include at least one CRT-related data parameter associated with time (claims 1, 49 and 54) (Figs. 4a–c) to provide feedback to the clinician during use of therapy (column 8, lines 35–36); means for displaying information includes a graph (claims 53 and 56) (Fig. 7) and table of (claim 57)

trended data (column 12, TABLES 2–3) to indicate the total amount of some algorithmically derived measure of activity over a given period of time, such as day or an hour and to display formatted data in a human readable form (column 7, lines 16–18 and 31–37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stahmann to include at least one CRT-related data parameter associated with time (claims 1, 49 and 54) or means for displaying information includes a graph (claim 56) and table of (claim 57) trended data, as taught by Stone to provide feedback to the clinician during use of therapy and to indicate the total amount of some algorithmically derived measure of activity over a given period of time, such as day or an hour and to display formatted data in a human readable form.

9. Additionally, claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stahmann and Stone as applied to claim 49 above, and further in view of Schroeppel et al., U.S. Patent 5,749,900.

Neither Stahmann nor Stone discloses an alert corresponding to a status of a prescribed CRT. However, Schroeppel discloses an alert corresponding to a status of a prescribed CRT (column 9, lines 17–22) to communicate a patient's pending heart condition (column 9, lines 19–20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Stahmann and Stone to include an alert corresponding to a status of a prescribed CRT, as taught by Schroeppel to communicate a patient's pending heart condition (column 9, lines 19–20).

***Response to Arguments***

10. Applicant's arguments with respect to claims 29–60 have been considered but are moot in view of the new ground(s) of rejection.

11. Additionally, Examiner has cited the claimed limitations for claims 29–30 in the Schroeppel reference in paragraph 7 above. Specifically, the amended limitation of "data trends include at least one CRT-related data parameter associated with time" is met in the Schroeppel reference by "The peak detector measures the timing of the peak amplitude, such as the A–A, P–P, V–V, or R–R interval of the heart signal ..." (column 6, lines 61–column 7, lines 1–7). These intervals of the heart signal are CRT-related data parameters associated with time. The claimed limitation is further expanded upon in the remaining cited references in paragraph 7 above.

***Conclusion***

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

13. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
December 1, 2005
1 December 2005

GEORGE R. EVANISKO
PRIMARY EXAMINER
12/4/5